

IDS/#5  
JAN 22/02

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Xianzhang YU, et al.

Title: LYtic PEPTIDE PRODRUGS

Appl. No.: 09/938,623

Filing Date: 08/27/2001

Examiner: Unassigned

Art Unit: 1644



JTECH CENTER 1600/2900

**RECEIVED**

JAN 23 2002

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Submitted herewith on Form PTO-SB-08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

**RELEVANCE STATEMENTS**

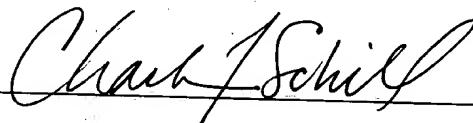
The relevance of Documents A1-A31 is described in the present specification.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO-SB-08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

By



Charles F. Schill  
Attorney for Applicant  
Registration No. 27,590

Date January 15, 2002

FOLEY & LARDNER  
Washington Harbour  
3000 K Street, N.W., Suite 500  
Washington, D.C. 20007-5143  
Telephone: (202) 945-6078  
Facsimile: (202) 672-5399

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO		Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>			
Date Submitted: December 28, 2001			
(use as many sheets as necessary)			
Sheet	1	of	3

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.
	A3	BLONDELLE et al., "Hemolytic and Antimicrobial Activities of the Twenty-Four Individual Omission Analogues of Melittin," <i>Biochemistry</i> , 1991, pp. 4671-4678, Vol. 30, American Chemical Society.
	A4	DEMPSEY et al., "Contribution of Proline-14 to the Structure and Actions of Melittin," <i>FEBS Letters</i> , 1991, pp. 240-244, Vol. 281, No. 1,2, Elsevier Science Publishers B.V.
	A5	LEIPPE et al., "Cytolytic and Antibacterial Activity of Synthetic Peptides Derived from amoebapore, the Pore-Forming Peptide of <i>Entamoeba Histolytica</i> ," <i>Proc. Natl. Acad. Sci. USA</i> , 1994, pp. 2602-2606, Vol. 91, Federation of European Biochemical Societies.
	A6	ANDRÄ et al., "Shortened Amoebapore Analogs with Enhanced Antibacterial and Cytolytic Activity," <i>FEBS Letters</i> , 1996, pp. 96-100, Vol. 385, Federation of European Biochemical Societies

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST 2). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.  
<sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, D.C. 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, D.C. 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				<b>Application Number</b>	09/938,623
Date Submitted: December 28, 2001				<b>Filing Date</b>	08/27/2001
(use as many sheets as necessary)				<b>First Named Inventor</b>	Xianzhang YU, et al.
Sheet	2	of	3	<b>Group Art Unit</b>	1644
				<b>Examiner Name</b>	Unassigned
				<b>Attorney Docket Number</b>	035879-0125

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS					
Examiner <i>W. Wallace</i>	Cite No. <i>1-7</i>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>b</sup>
JAN 17 2002 PMTM 6 TRADEMARK OFFICE	A7	SHAI et al., "Diastereomers of Cytolysins, a Novel Class of Potent Antibacterial Peptides," <i>Journal Biological Chemistry</i> , 1996, pp. 7305-7308, Vol. 271 No. 13, The American Society for Biochemistry and Molecular Biology, Inc.			
	A8	WERKMEISTER et al., "The Effect of Sequence Variations and Structure on the Cytolytic Activity of Melittin Peptides," <i>Biochimica et Biophysica Acta</i> , 1993, pp. 50-54, Vol. 1157, Elsevier Science Publishers B.V.			
	A9	LEIPPE et al., "Pore-Forming Peptide of Pathogenic <i>Entamoeba Histolytica</i> ," <i>Proc. Natl. Acad. Sci. USA</i> , 1991, pp. 7659-7663, Vol. 88, Federation of European Biochemical Societies.			
	A10	HOROSZEWCZ et al., "LNCaP Model of Human Prostatic Carcinoma <sup>1</sup> ," <i>Cancer Research</i> , 1983, pp. 1809-1818, Vol. 43, No. 4, American Association for Cancer Research.			
	A11	PINTO et al., "Prostate Specific Membrane Antigen, a Unique Glutamate Carboxypeptidase: A Review of Recent Findings," <i>The Prostate Journal</i> , 1999, pp. 15-26, Vol. 1, No. 1, Blackwell Science, Inc.			
	A12	LOPES et al., "Immunohistochemical and Pharmacokinetic Characterization of the Site-Specific Immunoconjugate CYT-356 Derived from Antiprostate Monoclonal Antibody," <i>Cancer Research</i> , 1990, pp. 6423-6429, Vol. 50, American Association for Cancer Research.			
	A13	TROYER et al., "Detection and Characterization of the Prostate-Specific Membrane Antigen (PSMA) in Tissue Extracts and Body Fluids," <i>Int. J. Cancer</i> , 1995, pp. 552-558, Vol. 62, Wiley-Liss, Inc.			
	A14	WALLRAPP et al., "A Novel Transmembrane Serine Protease (TMPRSS3) Overexpressed in Pancreatic Cancer <sup>1,2</sup> ," <i>Cancer Research</i> , 2000, pp. 2602-2606, Vol. 60, No. 10, American Association for Cancer Research.			
	A15	WRIGHT et al., "Expression of Prostate-Specific membrane Antigen in Normal, Benign, and Malignant Prostate Tissues," <i>Urol. Oncol.</i> , 1995, pp. 18-28, Vol. 1, Elsevier Science Inc., New York.			
	A16	PRAUSNITZ et al., "Electroporation of Mammalian Skin: A Mechanism to Enhance Transdermal Drug Delivery", <i>Proc. Natl. Acad. Sci. USA</i> ; 1993, pp. 10504-10508, Vol. 90, No. 22, Medical Sciences, NIH			
	A17	WALLACE et al., "Stand and Deliver: Getting Peptide Drugs into the Body", <i>Science</i> , 1993, pp. 912-913, Vol. 260, American Association for the Advancement of Science			
	A18	ANDREU et al., "Solid-Phase Synthesis of Cecropin A and Related Peptides", <i>Proc. Natl. Acad. Sci. USA</i> , 1983, pp. 6475-6479, Vol. 80, No. 21, Biochemistry, Biological Science			
	A19	ANDREU et al., "N-Terminal Analogues of Cecropin A: Synthesis, Antibacterial Activity, and Conformational Properties", <i>Biochemistry</i> , 1985, pp. 1683-1688, Vol. 24, No. 7, American Chemical Society			
	A20	FINK et al., "Design, Synthesis and Antibacterial Activity of Cecropin-Like Model Peptides", <i>Int. J. Peptide Protein Res.</i> , 1989, pp. 412-421, Vol. 33, No. 6, The Rockefeller University, New York, New York			

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, D.C. 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a "OMB Control Number" and is approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

<p style="text-align: center;">Substitute for form 1449B/PTO</p> <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p>Date Submitted: December 28, 2001 <i>(use as many sheets as necessary)</i></p>				<i>Do not file - a collection of information unless it contains a valid OMB control number.</i>	
				<b>Complete if Known</b>	
<b>Application Number</b>		09/938,623			
<b>Filing Date</b>		08/27/2001			
<b>First Named Inventor</b>		Xianzhang YU, et al.			
<b>Group Art Unit</b>		1644			
<b>Examiner Name</b>		Unassigned			
<b>Attorney Docket Number</b>		035879-0125			
Sheet	3	of	3		

**OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS**

EXAMINER - NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials O P E	Cite No. JAN 17 2002	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T6
A21	FINK et al., "The Chemical Synthesis of Cecropin D and an Analog with Enhanced Antibacterial Activity", J. of Biological Chemistry, 1989, pp. 6260-6267, Vol. 264, No. 11, American Society for Biochemistry and Molecular Biology, Inc. Rockefeller University, New York		
A22	ARGIOLAS et al., "Bombolitins, a New Class of Mast Cell Degranulating Peptides from the Venom of the Bumblebee Megabombus Pennsylvanicus", J. of Biological Chemistry, 1985, pp. 1437-1444, Vol. 260, No. 3, American Society of Biological Chemists, Inc.		
A23	YOUNG et al., "Characterization of a Member Pore-Forming Protein From Entamoeba Histolytica", J. Exp. Med. 1982, pp. 1677-1690, Vol. 156, No. 6, The Rockefeller University Press		
A24	LYNCH et al., "An Ion-Channel Forming Protein Produced by Entamoeba Histolytica", The EMBO Journal, 1982, pp. 801-804, Vol. 1, No. 7, IRL Press Limited, Oxford, England		
A25	YOUNG et al., "Molecular Mechanisms of Cytotoxicity Mediated by Entamoeba Histolytica: Characterization of a Pore-Forming Protein (PFP)", J. of Cellular Biochemistry, 1985, pp. 299-308, Vol. 29 No. 4, Alan R. Liss, Inc.		
A26	ROSENBERG et al., "Isolation, Characterization and Partial Purification of a Transferable Membrane Channel (Amoebapore) Produced by Entamoeba Histolytica", Molecular and Biochemical Parasitology, 1989, pp. 237-248, Vol. 33, No. 3, Elsevier Science Publishers B.V.		
A27	JANSSON et al., "Coding of Hemolysins Within the Ribosomal RNA Repeat on a Plasmid in Entamoeba Histolytica", Science, 1994, pp. 11440-11443, Vol. 263, American Association for the Advancement of Science		
A28	FERNANDEZ-LOPEZ et al., "Antibacterial Agents Based on the Cyclic D,L- $\alpha$ -Peptide Architecture", Letters of Nature, 2001, pp. 452-455, Vol. 412		
A29	WOODLE et al., "Prolonged Systemic Delivery of Peptide Drugs by Long-Circulating Liposomes: Illustration with Vasopressin in the Brattleboro Rat", Pharmaceutical Research, 1992, pp. 260-265, Vol. 9, No. 2, Plenum Publishing Corporation		
A30	HUSE et al., "Generation of a Large Combinatorial Library of the Immunoglobulin Repertoire in Phage Lambda", Science, 1989, pp. 1275-1281, Vol. 246, Research Article		
A31	COOMBS et al., "Substrate Specificity of Prostate-Specific Antigen (PSA)", Chemistry & Biology, 1998, pp. 475-488, Vol. 5, No. 9, Research Paper		

Examiner Signature		Date Considered
-----------------------	--	--------------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, D.C. 20231.